

## REMARKS

Claims 1, 2 and 4 to 7 and 9 are in the application. Claims 8 and 10 have been cancelled. Applicants reserve their right to file continuation application on all cancelled or deleted subject matter. Claim 1 has been amended. Claim 8 has been added as an optional component into Claim 1. Support for the amendment lie in the specification on page 3, lines 26 to 30. No new matter is believed added.

The specification has been amended to correspond to US Practice.

The Examiner comments that the Information Disclosure Statement previously submitted upon national stage entry is not in compliance. Applicants advise the Examiner that these references are cited on the International Search Report from the PCT application. WIPO actually forwards these references to the respective countries by WIPO and are consequently Applicants are not required to actually forward them. However, Applicants are resubmitting the best available copy herewith along with the File Wrapper and Oppositions cited against the granted EP patent and the art cited therein for the Examiner review.

### **Rejection under 35 USC §112**

Claims 1 and 10 are rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse this rejection.

The Examiner objects to the term ‘prebiotics’ in the claim as being inconsistent with the specification stating a ‘prebiotic effect’.

A prebiotic as defined by Wikipedia:

“**Prebiotics** are non-digestible food ingredients that stimulate the growth and/or activity of bacteria in the digestive system which are beneficial to the health of the body. They were first identified and named by Marcel Roberfroid in 1995. They are considered a functional food.”

Consequently whether one uses the term prebiotic or a food having a prebiotic effect, it is the same thing. However, in order to advance prosecution on the merits, Applicants have amended Claim 1 to recite the desired activity which is

“to promote the growth of beneficial bacteria and concomitantly reduce the growth of harmful bacteria in the gut of said human”.

In view of these remarks and amendments, reconsideration and withdrawal of the rejection to the claims under 35 USC §112, second paragraph is respectfully requested.

**Rejection under 35 USC §102**

Claims 1, 2, 4, 5, 9, and 10 are rejected under 35 USC §102 as being anticipated by Kontiokari et al. (BMJ Vol. 322). Applicants respectfully traverse this rejection.

The Examiner states that Kontiokari et al. discloses administering cranberry juice to women. Kontiokari et al does not state the use of cranberry as a prebiotic as the Examiner acknowledges. Consequently, all the limitations of claim 1 have not been addressed by the disclosure of Kontiokari et al.

The Examiner appears to be raising the issue of inherency by administration of the juice itself. “therefore with the inherent characteristics, at least some reduction n harmful bacteria would also inherent.

There is no evidence in Kontiokari et al. that cranberry juice has a dual effect of an increase in the beneficial gut bacteria along with a concomitant decrease in harmful gut bacteria. Kontiokari et al relates to the effect on cranberry juice on the urinary tract.

In order to advance prosecution on the merits however, Applicants have amended claim 1 to delete inclusion of Cranberry Juice.

In view of these remarks and amendments, reconsideration and withdrawal of the rejection to the claims is respectfully requested.

### **Rejection under 35 USC §103**

Claims 1, 2 and 4- 9, and 10 are rejected under 35 USC §103 as being unpatentable over Castleberry (US6,020,016) in view of De Jong et al. (US6,783,780) and Leahy et al. (Pharm Bio, Vol. 40, 2002). Applicants respectfully traverse this rejection.

Castleberry teaches a juice product which contains added glucans as an ingredient to produce various effects in humans, such as a change in cholesterol levels (see Col. 2, lines 7-8). In contrast to Castleberry, the juices as administered herein do not require additional fortification. Castleberry does not disclose a prebiotic effect achieved by administering dark fruit in an orally ingestible form

The Examiner appears to cite the De Jong et al. patent for the teaching of non-digestible oligosaccharides which are prebiotics and can be “placed in fruit drinks”.

Again this would require the addition of non digestible oligosaccharides to a composition which is not taught by the invention herein. Juices already contain a very low level of oligosaccharides and soluble saccharides. De Jong et al. teaches the use of these non digestible oligosaccharides in significantly increased levels, e.g.40-80% (see column 4, tablet 1. De Jong et al also adds these oligosaccharides to a probiotic composition. As noted above, no additional oligosaccharides to the juice as used herein.

The Examiner cites Leahy for a disclosure that cranberries have been shown to have a prebiotic effect in the gastrointestinal tract “ However, this citation on page 53 is referencing the previously cited Kontiokari et al. study as supporting a prebiotic effect of cranberry juice”. However, this is incorrect. As the Examiner concluded Kontiokari does NOT teach this effect. Therefore, no reliance should be placed upon this incorrect conclusion of the Kontiokari et al. reference.

Leahy focuses on cranberry juice and its effect on urinary tract infection. (see page 51, 2<sup>nd</sup> column – approx lines 21-25 and the summary on page 53. The method of use as claimed herein is not administering an effective amount of dark fruit for treating

urinary tract infections, but for increasing the amount of beneficial bacteria in the gut, along with a concomitant decrease in the amount of harmful bacteria there as well.

The data in the spec (tables 4-6) demonstrates that the beneficial bacteria all increase in numbers – *Bifidobacteria*, *Lactobacilli*, *E. recatle* & *limnosum* while the harmful bacteria – *Bacterioides* and *C. histolyticum* all decrease, when contacted with three different juices.

The primary Castleberry reference actually teaches away from the claimed invention in that addition of glucans is required to achieve the desired effect as it the case as well with De Jong et al. None of the references recognize one of the required effects, e.g. a decrease of the harmful bacteria when administered in an effective amount. Consequently, all of the limitations of claim 1 are not disclosed nor suggested by the references herein. To further advance prosecution on the merits, the claims have been amended to recite “consisting of” .

In view of these remarks and amendments, reconsideration and withdrawal of the rejection to the claims is respectfully requested.

#### CONCLUSION

34If it would expedite the prosecution of this application, the Examiner is invited to confer with the Applicants' undersigned attorney. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case, the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

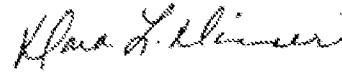
Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. If any additional fees or

USSN: 10/598,760

Art Unit: 1794

charges are required by this paper the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Dara L. Dinner".

Dara L. Dinner  
Attorney for Applicant  
Registration No. 33,680

GLAXOSMITHKLINE  
Corporate Intellectual Property UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
Phone (610) 270-5017  
Facsimile (610) 270-5090